10CV378 RHK/FLN

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
COURT FILE NO.: _____

Etta Henry,

Plaintiff,

vs.

COMPLAINT AND DEMAND FOR JURY TRIAL

GE HEALTHCARE, a division of **GENERAL ELECTRIC COMPANY,** a New York corporation; **GE HEALTHCARE, INC.**, a Delaware corporation, f/k/a **AMERSHAM HEALTH, INC.**, a foreign corporation, d/b/a GE HEALTHCARE; **GE HEALTHCARE IITS LLC,** a Delaware corporation, and **GE HEALTHCARE IITS USA CORP**, a Vermont corporation,

Defendants.

Plaintiff Etta Henry, for her Complaint against the Defendants – GE Healthcare, a division of General Electric Company, a New York corporation; GE Healthcare, Inc., a Delaware corporation, f/k/a Amersham Health, Inc., a foreign corporation, d/b/a GE Healthcare; GE Healthcare IITS LLC, a Delaware corporation; and GE Healthcare IITS USA Corp., a Vermont corporation, states and alleges as follows:

PARTIES

1. Etta Henry is an individual above the age of nineteen (19) and is a resident of Huntsville, Madison County, Alabama.

2. At all times material hereto, Defendant GE Healthcare, a division of General Electric Company, was and is a corporation organized, existing, and doing business under and by

virtue of the laws of the state of New York, with its global headquarters located in Chalfront St. Giles, Buckinghamshire, United Kingdom.

3. At all times material hereto, Defendant GE Healthcare, Inc., was and is a Delaware corporation with its principal place of business in New Jersey.

4. At times material hereto, Defendant Amersham Health, Inc., was a foreign corporation with its principal place of business in New Jersey, and was doing business as GE Healthcare.

5. At times material hereto, Defendant Amersham Health, Inc. has conducted business in the State of Minnesota under the assumed name of GE Healthcare.

6. At times material hereto, GE Healthcare has been an active assumed name registered with the Minnesota Secretary of State by Amersham Health, Inc.

7. At times material hereto, Defendant GE Healthcare, Inc. was known as Amersham Health, Inc.

8. At all times material hereto, Defendant GE Healthcare IITS, LLC, was and is a primary business unit of GE Healthcare with its business headquarters located in Barrington, Illinois.

9. At all times material hereto, Defendant GE Healthcare IITS USA Corp. was and is a primary business unit of GE Healthcare, Inc., with its business headquarters located in Burlington, Vermont.

10. All entities identified in paragraph 2 through 9, above, are collectively referred to as "Defendants."

11. At all time material hereto, Defendants have conducted business in the State of Minnesota, with CT Corporation System, Inc. of Minneapolis, Minnesota serving as the agent for service of process for each Defendant.

12. Defendants include any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors, and assigns, and their present officers, directors, employees, agents, representatives, and other persons acting on their behalf.

JURISDICTION AND VENUE

13. Plaintiff repeats and re-alleges paragraphs 1 through 12 as if fully set out herein.

14. Given the amount in controversy and the nature of claims plead *infra*, this Court has subject matter jurisdiction over this matter.

15. This Court has personal jurisdiction over Defendants.

16. Venue is proper in this Court with respect to Defendants as per binding Minnesota authority.

FACTS

Radiation: Its Uses and Effects

17. Plaintiff repeats and re-alleges paragraphs 1 through 16 as if fully set out herein.

18. The common name for energy emitted from X-ray machines is ionizing radiation. The name indicates that the radiation has sufficient energy to ionize atoms and molecules. Ionization takes place when radiation changes the charge of the atoms or molecules it strikes. As used throughout this Complaint, the term "radiation" means ionizing radiation.

19. Doctors use radiation for diagnostic applications. In fact, one of the main tools available for diagnosis is computer aided tomography (a "CT scan.") A CT scan is a diagnostic imaging procedure that uses a combination of X-ray radiation and computer technology to produce cross-sectional scans or "slices," both horizontally and vertically, of the human body.

20. However, CT scans are more detailed than a standard X-ray. In computer tomography, the X-ray beam moves in a circle around the body. This allows many different views of the same organ or structure, and provides much greater detail. The X-ray information is sent electronically to a computer, which interprets the X-ray data and displays it in a two-dimensional form on a monitor. The CT scan has become an important tool in medical imaging to supplement X-rays and medical ultrasonography. CT scanning of the head is typically used to detect, among other things, bleeding, brain injury, skull fractures, aneurysm, strokes, a blood clot or bleeding within the brain after a patient exhibits symptoms of an injury or other problem.

21. Under normal circumstances, a head CT scan is generally painless, non-invasive, and accurate. The effective radiation from a CT scan is usually about 1 to 2 millisievert (mSv), equivalent to the background radiation dose the average person receives over four to six months. The risk of developing a brain tumor or other cancer from this radiation exposure is generally not a major health concern.

22. However, increased levels of radiation exposure can also have negative consequences known as somatic effects. Somatic effects are, generally speaking, health risks for which the probability of a negative occurrence is considered to be a function of a dose of radiation above a threshold amount.

23. Somatic effects result from cells in the body being exposed to an amount of radiation which causes ionization of the chemical elements therein. This ionization either results in the immediate death of the cell or results in a change in the genetic code of the cells.

24. Fortunately, most chromosome changes are lethal to the affected cell. In some cases, however, they may cause abnormal growth patterns ultimately resulting in the formation of benign or cancerous tumors.

25. Hence, radiation is always damaging to the cells or tissue of the body. For this reason concentrated radiation doses are directed at cancer growth areas in the body – to kill or damage the cancerous tissue so that the growth and multiplication of the cancer is stopped.

26. As radiation can have both useful and detrimental effects, it was important to establish guidelines for those likely to encounter such exposure (e.g. healthcare workers, those undergoing CT scans, etc.). Guidelines have been established by the International Commission on Radiological Protection (the "ICRP"). The ICRP adopted the following principles for the use of radiation: 1) The application of radiation should be useful; and 2) The radiation dose should be as low as reasonably achievable (the "ALARA Principle").

The CT Machines
Manufactured by GE Defendants

27. The CT machines manufactured and sold by Defendants comprise a radiation-emitting technology that was researched, developed, designed, formulated, fabricated, tested, manufactured, produced, processed, assembled, inspected, marketed, labeled, promoted, packaged, advertised for sale, sold or otherwise placed into the stream of commerce by the Defendants.

28. The Defendants knew and/or intended that the CT imaging equipment manufactured by the Defendants would be used in the treatment of a patient's condition, and

specifically for the diagnosis of human illness, including the diagnosis of stroke or other brain-related disease, and that patients would be exposed to a small amount of radiation in the course of the radiological procedures.

29. On or about October 9, 2009, the U.S. Food and Drug Administration ("FDA") released a notification to healthcare professionals indicating that it had become aware of radiation overexposures during perfusion CT imaging performed to aid in the diagnosis of stroke. The FDA notice stated that, for an 18 month period, beginning in February, 2008, 206 patients had received radiation doses that were approximately eight times the expected level. Instead of receiving the expected dose of 0.5 Gray (abbreviated as "Gy") (maximum) to the head, these patients received 3-4 Gy. The FDA further indicated that "the magnitude of these overdoses and their impact on affected patients were significant."

30. The FDA further indicated that it had commenced a safety investigation, suggesting that the situation may reflect more widespread problems with CT quality assurance programs. A nationwide alert was issued by the FDA warning hospitals to check CT brain scan procedures. Huntsville Hospital received the warning. Hence, all Defendants knew or should have known of the risks of radiation overexposure which would result from using CT machines manufactured by the GE Defendants.

31. Due to the actions of Defendants in either the lack of including or maintaining appropriate safety functions, implementing confusing methodology, or some other cause, the machines in question have emitted a much higher level of radiation than was either intended or is reasonably safe.

32. The radiation exposure which results is a proven hazardous substance inasmuch as same is a known carcinogen.

33. The exposure to a greater level of radiation than was intended results in a significantly-increased risk of contracting serious, latent diseases and other somatic effects.

34. The CT machines manufactured by the Defendants do not meet the guidelines established by the ICRP.

Plaintiff's CT Scan Resulting in a Radiation Overexposure

35. On or about February 13, 2004, Etta Henry received a CT maxillofacial without contrast scan at Huntsville Hospital. The scan was performed by employees of Huntsville Hospital using equipment that was, based upon information and belief, manufactured by the GE Defendants.

36. As a result of the scan, Ms. Henry discovered she was suffering from multiple myeloma, a type of cancer that is linked to radiation poisoning, other symptoms of radiation poisoning, and, according to experts' present understanding, the genetic material of her brain cells was immediately damaged.

37. Either due to the lack of appropriate safety functions, inadvertence, negligence, confusing methodology, some other cause, or a combination of the foregoing, Ms. Henry was subjected to a CT scan which emitted a much-higher level of radiation than was either intended or is considered reasonably safe by the ICRP.

38. The radiation to which Ms. Henry was exposed is a proven hazardous substance inasmuch as same is a known carcinogen.

39. As a proximate result of the exposure to a greater level of radiation than was intended due to Defendants' negligence and/or other behavior, Ms. Henry was immediately injured and now has a significantly-increased risk of contracting serious, latent diseases and/or other samatic effects.

CAUSE OF ACTION
Negligence

40. Plaintiff repeats and re-alleges paragraphs 1 through 39 as if fully set out herein.

41. At all times mentioned herein, the Defendants had a duty to properly research, design, formulate, test, manufacture, produce, process, assemble, inspect, maintain, market, label, distribute, prepare for use, sell, and adequately warn of the risks and dangers of CT medical imaging machines, including a duty to assure that such devices did not cause patients receiving CT scans, including CT maxillofacial without contrast scans, to suffer from unreasonable and dangerous health risks and exposure to possible harm, loss or injury.

42. At all times mentioned herein, the Defendants failed to exercise ordinary care and negligently and carelessly researched, designed, formulated, tested, manufactured, produced, processed, assembled, inspected, marketed, labeled, maintained, distributed, prepared for use, sold, rented, leased, maintained, and repaired and failed to adequately test, research, and warn of the risks and dangers of CT imaging machines.

43. At all times mentioned herein, the Defendants breached their duty to Plaintiff, and were negligent in researching, designing, formulating, testing, maintaining, manufacturing, producing, processing, assembling, inspecting, marketing, labeling, distributing, preparing for use, selling, renting, leasing, maintaining, and repairing, and failing to adequately warn of the risks and dangers of CT imaging machines in that the GE Defendants:

a. Failed to use ordinary care in designing and manufacturing CT imaging machines so as to avoid the aforementioned health risks to Plaintiff;

b. Failed to accompany CT imaging machines with proper warnings regarding the possible adverse health effects associated with the use of such machines and of the severity and duration of such possible adverse effects;

c. Failed to conduct adequate pre-clinical testing and post-marketing surveillance to determine the safety and side effects of CT scans, including, among other things, CT maxillofacial without contrast scans;

d. Failed to provide adequate training to physicians, medical technicians, and other health care providers as to the possible adverse health effects associated with the use of CT scans, including, among other things, CT maxillofacial without contrast scans, and the severity and duration of such adverse effects;

e. Failed to warn Plaintiff, either directly or indirectly, orally or in writing, about the need for regular monitoring and maintenance of CT scanners to ensure that excessive radiation exposure does not occur;

f. Failed to adequately maintain and/or service the CT scanners in question;

g. Failed to include or provide adequate warnings about CT scans that would alert Plaintiff, physicians, medical technicians, hospitals, and clinics, to the potential risks, and the nature, scope, severity, and duration of any serious health effects of CT scans, including CT maxillofacial without contrast scans;

h. Continued to promote the desirability and safety of CT scans, including CT brain perfusion scans, while providing little or no warnings about the serious injuries and health risks associated with CT scans, including CT maxillofacial without contrast scans, which may have dissuaded physicians and other medical providers from monitoring patient exposure to excessive radiation levels;

i. Failed to adequately test and/or warn about the possible serious health effects of CT scans, including excessive patient exposure to radiation; and/or

j. Delayed warnings of and then failed to provide adequate warnings about the serious injuries and health risks associated with CT scans, including CT brain perfusion scans, which may have dissuaded physicians and other medical providers from monitoring patient exposure to excessive radiation levels.

44. As a further direct, proximate and legal result of the negligence of the Defendants as alleged herein, Plaintiff has incurred and will continue to incur medical, hospital and related expenses, pain and suffering and severe mental anguish.

45. As a further direct and proximate result of the acts and omissions of the Defendants, Plaintiff has sustained and will in the future sustain loss of earnings, loss of earning capacity, and other economic damages according to proof at the time of trial.

46. As a further direct and proximate result of the acts and omissions of the Defendants, Plaintiff has suffered and will continue to suffer severe and serious physical and emotional damage in an amount to be ascertained according to proof at the time of trial and in excess of the jurisdictional limit of this court.

47. Accordingly, Plaintiff seeks, and is entitled to, the relief requested against the Defendants.

RELIEF REQUESTED

WHEREFORE, Plaintiff prays that the Court:

1. Grant her a jury trial of the issues in this case.

2. Declare that Defendants acted negligently and that the equipment manufactured at issue and/or the equipment was negligently designed and/or manufactured, was accompanied by

inadequate safety warning, was accompanied by inadequate safety features or was accompanied by inadequate and overly-complicated instructions.

3. Award compensatory damages to Plaintiff against Defendants for both past and future medical expenses, lost wages, pain and suffering and severe mental anguish;

4. Award such other, further and different relief, including equitable, that the Court deems just and proper.

PLAINTIFF DEMANDS TRIAL BY JURY

Dated: February 11, 2010

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